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Author and original designer of the OneLife Basic Nutrition System (BNS-2D): Carlos Daniel Borrego Romero.

ANNEX B – Standardized Preparation and Safe Production Protocols for the OneLife Basic Nutrition System (BNS-2D)

B.1. Purpose and scope

B.1.1. This Annex establishes standardized procedures for the preparation, handling and production of the OneLife Basic Nutrition System (BNS-2D) in all approved presentations, in order to ensure correct portioning, nutritional adequacy and microbiological safety.

B.1.2. It applies to manufacturers, government and non-governmental implementing partners, health and social-service facilities, schools, community centers and humanitarian operations using the OneLife system.

B.1.3. Where national regulations or context-specific guidelines for food preparation and hygiene are more stringent than the requirements set out in this Annex, such national provisions shall prevail, provided that they do not compromise the nutritional objectives of the OneLife system.

B.2. Standardized portioning and mixing – powder presentation

B.2.1. Standard portion size per dose.

Each adult standard dose of the powder presentation shall consist of 80–100 g of dry product reconstituted with 300–400 ml of safe drinking water, as specified in the main body of the protocol.

B.2.2. Approved measuring devices.

Implementers shall use standardized measuring devices (for example, calibrated scoops or weighing scales) that correspond to the gram quantities defined above.

Household utensils (cups, spoons) may be used only when they have been calibrated and clearly marked to approximate the required weight and volume.

B.2.3. Stepwise preparation instructions – individual dose.

For each dose, the following steps shall be followed:

1. Wash hands with soap and safe water and dry them with a clean towel or air-dry.
2. Ensure that the container used for mixing is clean and, where feasible, has been washed with hot water and soap and allowed to dry.

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3. Measure the required amount of safe drinking water (300–400 ml) into the container.
4. Add the measured quantity of powder (80–100 g) to the water.
5. Stir or shake vigorously until the powder is fully dispersed and no visible lumps remain.
6. Consume the reconstituted product immediately after preparation; do not store at ambient temperature for prolonged periods.

B.2.4. Batch preparation for multiple beneficiaries.

Where OneLife is prepared in bulk (for example, in schools or community feeding centers), the following additional measures shall be applied:

1. Use standardized, verified recipes specifying total powder weight, water volume, expected number of portions and serving size per person.
2. Use appropriately sized mixing vessels and utensils that can be cleaned and sanitized between batches.
3. Keep the prepared mixture covered and protected from dust, insects and direct sunlight.
4. Serve all portions within two hours of preparation; discard any remaining product after this period, unless local food-safety authorities provide more stringent time limits.

B.3. Safe preparation and handling – general requirements

B.3.1. Water quality.

Where the powder presentation is used, water shall meet national or WHO standards for drinking-water quality.

If only untreated water is available, it shall be made safe through boiling, chlorination or filtration, according to national guidelines.

B.3.2. Hygiene practices.

All persons preparing or serving OneLife shall:

- Wash hands with soap and safe water before preparation, before feeding infants or young children, after using the toilet and after handling waste.
- Keep fingernails short and clean; avoid preparing food when ill with vomiting, diarrhea or fever.
- Use clean utensils and serving containers; avoid direct contact between hands and the prepared product whenever possible.

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B.3.3. Storage of dry product.

Dry powder and nutritional bars shall be stored:

- In their original, unopened packaging until use.
- In a cool, dry, well-ventilated place, away from direct sunlight and sources of moisture.
- Off the floor and protected from rodents, insects and other pests.

B.3.4. Handling of opened packages.

Once a sachet or multipack is opened:

- Reseal or close the package as tightly as possible if the full content is not used immediately.
- Use remaining product as soon as feasible and within the period indicated by the manufacturer.
- Avoid transferring dry product to unlabelled or inappropriate containers that could lead to confusion or contamination.

B.4. Bar presentation – portioning and use

B.4.1. Standard unit and dose equivalence.

The nutritional bar presentation shall be manufactured such that a clearly defined number of bars (for example, one bar or two bars) constitutes one adult standard dose equivalent in energy and nutrients to the powder dose.

B.4.2. Labelling and portion guidance.

Packaging shall clearly indicate:

- The number of bars per dose for adults.
- Recommended adjustments for children and specific groups, where applicable.
- Instructions encouraging consumption of the full dose within a reasonable time and with access to safe drinking water.

B.4.3. Use and distribution in the field.

When distributing bars:

- Avoid splitting individual bars among many people in ways that would systematically reduce intake below the intended dose.
- Provide guidance to beneficiaries to chew thoroughly and, where possible, to drink safe water alongside the bar.

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- Store bars under conditions that prevent melting, deformation or moisture uptake.

B.5. Production protocols – factory level

B.5.1. Good manufacturing practice (GMP).

Manufacturers of OneLife products shall operate under documented Good Manufacturing Practice systems covering raw material reception, storage, processing, packaging and distribution.

B.5.1 bis. Implementing partners and end-users shall not modify the composition of OneLife products by adding or removing ingredients at factory level or in the field, unless such modifications are authorized through a formal reformulation process that demonstrates nutritional and safety equivalence.

B.5.2. Process control for powder presentation.

Core process steps shall include:

- Accurate weighing and dosing of all ingredients in accordance with the approved formulation.
- Homogeneous dry mixing to ensure uniform distribution of macronutrients and micronutrients.
- Controlled microencapsulation of oils when such technology is used.
- Filling and hermetic sealing of sachets or containers with validated equipment.

B.5.3. Process control for bar presentation.

For the bar form, the manufacturing process shall ensure:

- Uniform mixing of dry and semi-solid ingredients to avoid nutrient segregation.
- Consistent bar weight and dimensions within specified tolerances.
- Adequate compaction or extrusion to maintain structural integrity during storage and transport.
- Rapid cooling and packaging to minimize risk of microbial growth and oxidation.

B.5.4. Critical control points.

Each manufacturing site shall identify and monitor critical control points, including:

- Raw-material acceptance criteria.
- Temperature and humidity control during processing and storage.
- Metal detection or other contamination-prevention measures.
- Final moisture content and water activity of the product.

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B.6. Quality-control testing and release criteria

B.6.1. Routine batch testing.

Each production batch of OneLife powder and bars shall be tested, at a minimum, for:

- Moisture content.
- Microbiological indicators, including absence of key pathogens.
- Nutrient content for selected macronutrients and micronutrients as specified in the main protocol.

B.6.2. Stability and shelf-life verification.

Manufacturers shall conduct initial and periodic stability studies under typical storage conditions to confirm that:

- Nutrient levels remain within specified ranges up to the end of shelf life.
- Organoleptic characteristics (appearance, smell, taste, texture) remain acceptable.
- No unacceptable physical changes (caking, separation, rancidity) occur.

B.6.3. Traceability and recall.

Products shall be labelled with batch and production date codes that allow full traceability.

Each manufacturer and implementing partner shall maintain procedures for rapid recall and investigation in the event of safety concerns or non-conformities.

B.7. Field implementation, training and supervision

B.7.1. Standard operating procedures (SOPs).

Implementing agencies shall develop simple, context-adapted SOPs for facility- and community-level preparation, based on the requirements in this Annex.

B.7.2. Training of personnel.

All staff involved in preparation, serving, storage or supervision of OneLife shall receive training covering:

- Correct portioning and mixing for powder and bar presentations.
- Key hygiene practices and contamination risks.
- Recognition and management of damaged, expired or suspect product.

B.7.3. Supportive supervision and audits.

Supervisory visits shall periodically verify:

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- Adherence to preparation and hygiene protocols.
- Correct use of measuring devices and portion sizes.
- Proper storage conditions and stock management.

Findings from supervisory visits and audits shall be documented and, where recurrent issues are detected, corrective action plans shall be agreed and implemented with clear timelines and responsibilities.

B.7.4. Communication with beneficiaries.

Where appropriate, pictogram-based instructions and simple messages shall be provided to beneficiaries to reinforce:

- The importance of consuming the full dose.
- The need to use safe water with powder, and to accompany bars with water where possible.
- Basic storage and handling precautions at household level.

B.8. Reporting of safety and acceptability events

B.8.1. Implementing partners shall establish simple and reliable mechanisms for reporting specific events related to the safety and acceptability of OneLife products, including but not limited to gastrointestinal intolerance, suspected allergic reactions, and systematic rejection or refusal by beneficiaries.

B.8.2. Reports shall, as far as practicable, include information on the type of event, product presentation (powder or bar), batch number, context of use, affected population group and any immediate action taken.

B.8.3. National authorities and coordinating agencies are encouraged to compile and periodically analyse these reports as part of a global “nutrition pharmacovigilance” system, in order to detect patterns, identify potential product- or context-specific issues and inform timely corrective and preventive actions.

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